JUN - 7 2010

510(k) Summary of Safety and Effectiveness

This summary of safety and effectiveness information is being submitted in accordance with the requirements of The Safety Medical Devices Act of 1990 (SMDA 1990) and 21 CFR Part 807.92.

Assigned 510(k) Number: K091845

Date of Summary Preparation: May 27, 2009

Manufacturer:
Phadia AB
Rapsgatan 7
SE-751 37 Uppsala, Sweden

510 (k) Contact Person:
Martin Mann
Regulatory Affairs Manager
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Portage, Mi 49002, USA
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Device Name:
EliA™ Cardiolipin IgG Immunoassay
EliA™ Cardiolipin IgM Immunoassay
EliA™ β2-Glycoprotein I IgG Immunoassay
EliA™ β2-Glycoprotein I IgM Immunoassay
EliA™ APS Positive Control

Common Name:
Cardiolipin autoantibody immunological test system
β2-Glycoprotein I autoantibody immunological test system

Classification

Product Name	Product Code	Class	CFR
EliA™ Cardiolipin IgG	MID	II	866.5660
EliA™ Cardiolipin IgM	MID	II	866.5660
EliA™ β2-Glycoprotein I IgG	MSV	II	866.5660
EliA™ β2-Glycoprotein I IgM	MSV	II	866.5660
EliA™ APS Positive Control	JJY	I	862.1660

Substantial Equivalence to

Varelisa Cardiolipin IgG Antibodies	K020752
Varelisa Cardiolipin IgM Antibodies	K020758
Varelisa ß2-Glycoprotein I IgG Antibodies	K040449
Varelisa ß2-Glycoprotein I IgM Antibodies	K040451

Intended Use Statements of the New Devices

1) EliA Cardiolipin IgG is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to cardiolipin in human serum and plasma (Li-heparin, EDTA, citrate) to aid in the diagnosis of antiphospholipid syndrome (APS) as well as thrombotic disorders related to secondary antiphospholipid syndrome in conjunction with other laboratory and clinical findings. EliA Cardiolipin IgG uses the the EliA IgG method on the instruments Phadia 100 and Phadia 250.

2) EliA Cardiolipin IgM is intended for the in vitro semi-quantitative measurement of IgM antibodies directed to cardiolipin in human serum and plasma (Li-heparin, EDTA, citrate) to aid in the diagnosis of antiphospholipid syndrome (APS) as well as thrombotic disorders related to secondary antiphospholipid syndrome in conjunction with other laboratory and clinical findings. EliA Cardiolipin IgM uses the the EliA IgM method on the instruments Phadia 100 and Phadia 250.

3) EliA β2-Glycoprotein I IgG is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to β2-Glycoprotein I in human serum and plasma (Li-heparin, EDTA, citrate) to aid in the diagnosis of antiphospholipid syndrome (APS) a as well as thrombotic disorders related to secondary antiphospholipid syndrome in conjunction with other laboratory and clinical findings. EliA β2-Glycoprotein I IgG uses the the EliA IgG method on the instruments Phadia 100 and Phadia 250.

4) EliA β2-Glycoprotein I IgM is intended for the in vitro semi-quantitative measurement of IgM antibodies directed to β2-Glycoprotein I in human serum and plasma (Li-heparin, EDTA, citrate) to aid in the diagnosis of antiphospholipid syndrome (APS) as well as thrombotic disorders related to secondary antiphospholipid syndrome in conjunction with other laboratory and clinical findings. EliA β2-Glycoprotein I IgM uses the the EliA IgM method on the instruments Phadia 100 and Phadia 250.

5) EliA APS Positive Control 100 is intended for laboratory use in monitoring the performance of in vitro measurement of antibodies to cardiolipin and ß2-Glycoprotein I with Phadia 100 using the EliA IgG or IgM method.

6) EliA APS Positive Control 250 is intended for laboratory use in monitoring the performance of in vitro measurement of antibodies to cardiolipin and ß2-Glycoprotein I with Phadia 250 using the EliA IgG or IgM method.

Special condition for use statement

The device is for prescription use only.

Special instrument requirements

Phadia® 100/Phadia® 250 are fully automated immunoassay analyzers, which include software for evaluation of test results.

General Description of the New Devices

The new devices belong to a fully integrated and automated system for immunodiagnostic testing. It comprises a Fluorescence-Immunoassay test system using EliA single wells as the solid phase and is intended to be performed on the instruments Phadia 100 and Phadia 250.

The conjugate for the EliA IgG method is mouse anti-human IgG beta-galactosidase, which uses 4-Methylumbelliferyl-ßD-Galactoside as substrate.

The conjugate for the EliA IgM method is mouse anti-human IgM beta-galactosidase, which uses 4-Methylumbelliferyl-ßD-Galactoside as substrate.

The total IgG and IgM calibration is based on a set of six WHO-standardized IgG and IgM Calibrators, respectively, derived from human serum. They are used to establish an initial calibration curve, which may be used for up to 28 days on additional assays and can be stored by the instrument. Each additional assay includes calibrator (curve) controls that have to recover in defined ranges to ensure that the stored calibration curve is still valid. The Fluorescence-Immunoassay test system includes test-, method-specific and general reagents that are packaged as separate units.

Test Principle of the New Devices

The EliA Wells are coated with the following antigens:

Test	Antigen coated to the wells:
EliA Cardiolipin IgG/IgM	Bovine cardiolipin antigen and bovine β2-glycoprotein as co-factor
EliA β2-Glycoprotein I IgG/IgM	Human β2-Glycoprotein I antigen

If present in the patient's specimen, antibodies to the antigens mentioned above bind to their specific antigen. After washing away non-bound antibodies, enzyme-labeled antibodies against human IgG or IgM antibodies (EliA IgG or IgM Conjugate) are added to form an antibody-conjugate complex. After incubation, non-bound conjugate is washed away and the bound complex is incubated with a Development Solution. After stopping the reaction, the fluorescence in the reaction mixture is measured. The higher the response value, the more specific IgG or IgM is present in the specimen. To evaluate test results, the response for patient samples is compared directly to the response for calibrators.

Device Comparison

The new and the predicate devices both represent non-competitive solid phase ELISAs. Both IVDs are used as an aid in the diagnosis of certain autoimmune disease thrombotic disorders, such as those secondary to systemic lupus erythematosus (SLE) or other lupus-like thrombotic diseases.

Laboratory equivalence

The comparability of predicate device and new device is supported by a data set including

- **results obtained within a comparison study between new and predicate device**
- **results obtained for clinically defined sera**
- **results obtained for samples from apparently healthy subjects (normal population).**

In summary, all available data support that the new devices are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

JUN 07 2010

Phadia US Inc.
c/o Mr. Martin Mann
Regulatory Affairs Manager
4169 Commercial Avenue
Portage, MI 49002

Re: k091845

Trade/Device Name:	EliA™ Cardiolipin IgG on the Phadia 100 and 250 instruments EliA™ Cardiolipin IgM on the Phadia 100 and 250 instruments EliA™ ß2-Glycoprotein I IgG on the Phadia 100 and 250 instruments EliA™ ß2-Glycoprotein I IgM on the Phadia 100 and 250 instruments EliA™ APS Positive Control 100 EliA™ APS Positive Control 250
Regulation Number:	21 CFR §866.5660
Regulation Name:	Multiple Autoantibodies Immunological Test System
Regulatory Class:	Class II
Product Code:	MID, MSV, JJY
Dated:	June 3, 2010
Received:	June 4, 2010

Dear Mr. Mann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan, Ph.D
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): k091845

Device Name: **EliA™ Cardiolipin IgG**

Indication For Use:

EliA Cardiolipin IgG is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to cardiolipin in human serum and plasma (Li-heparin, EDTA, citrate) to aid in the diagnosis of antiphospholipid syndrome (APS) as well as thrombotic disorders related to secondary antiphospholipid syndrome in conjunction with other laboratory and clinical findings. EliA Cardiolipin IgG uses the EliA IgG method on the instrument Phadia 100.

Prescription Use __√____ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Reena Philip

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k091845

Indication for Use

510(k) Number (if known): k091845

Device Name: **EliA™ Cardiolipin IgG**

Indication For Use:

EliA Cardiolipin IgG is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to cardiolipin in human serum and plasma (Li-heparin, EDTA, citrate) to aid in the diagnosis of antiphospholipid syndrome (APS) as well as thrombotic disorders related to secondary antiphospholipid syndrome in conjunction with other laboratory and clinical findings. EliA Cardiolipin IgG uses the EliA IgG method on the instrument Phadia 250.

Prescription Use __√____ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Leena Philip

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k091845

Indication for Use

510(k) Number (if known): k091845

Device Name: **EliA™ Cardiolipin IgM**

Indication For Use:

EliA Cardiolipin IgM is intended for the in vitro semi-quantitative measurement of IgM antibodies directed to cardiolipin in human serum and plasma (Li-heparin, EDTA, citrate) to aid in the diagnosis of antiphospholipid syndrome (APS) as well as thrombotic disorders related to secondary antiphospholipid syndrome in conjunction with other laboratory and clinical findings. EliA Cardiolipin IgM uses the EliA IgM method on the instrument Phadia 100.

Prescription Use __√___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Leena Philip

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) k091845

Indication for Use

510(k) Number (if known): k091845

Device Name: **EliA™ Cardiolipin IgM**

Indication For Use:

EliA Cardiolipin IgM is intended for the in vitro semi-quantitative measurement of IgM antibodies directed to cardiolipin in human serum and plasma (Li-heparin, EDTA, citrate) to aid in the diagnosis of antiphospholipid syndrome (APS) as well as thrombotic disorders related to secondary antiphospholipid syndrome in conjunction with other laboratory and clinical findings. EliA Cardiolipin IgM uses the EliA IgM method on the instrument Phadia 250.

Prescription Use __√___ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k091845

Indication for Use

510(k) Number (if known): k091845

Device Name: **EliA™ β2-Glycoprotein I IgG**

Indication For Use:

EliA β2-Glycoprotein I IgG is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to β2-Glycoprotein I in human serum and plasma (Li-heparin, EDTA, citrate) to aid in the diagnosis of antiphospholipid syndrome (APS) as well as thrombotic disorders related to secondary antiphospholipid syndrome in conjunction with other laboratory and clinical findings. EliA β2-Glycoprotein I IgG uses the EliA IgG method on the instrument Phadia 100.

Prescription Use __√____ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k091845

Indication for Use

510(k) Number (if known): k091845

Device Name: **EliA™ β2-Glycoprotein I IgG**

Indication For Use:

EliA β2-Glycoprotein I IgG is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to β2-Glycoprotein I in human serum and plasma (Li-heparin, EDTA, citrate) to aid in the diagnosis of antiphospholipid syndrome (APS) as well as thrombotic disorders related to secondary antiphospholipid syndrome in conjunction with other laboratory and clinical findings. EliA β2-Glycoprotein I IgG uses the EliA IgG method on the instrument Phadia 250.

Prescription Use __√____ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Reena Philip

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k091845

Indication for Use

510(k) Number (if known): k091845

Device Name: **EliA™ β2-Glycoprotein I IgM**

Indication For Use:

EliA β2-Glycoprotein I IgM is intended for the in vitro semi-quantitative measurement of IgM antibodies directed to β2-Glycoprotein I in human serum and plasma (Li-heparin, EDTA, citrate) to aid in the diagnosis of antiphospholipid syndrome (APS) as well as thrombotic disorders related to secondary antiphospholipid syndrome in conjunction with other laboratory and clinical findings. EliA β2-Glycoprotein I IgM uses the EliA IgM method on the instrument Phadia 100.

Prescription Use __√____ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

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Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k091845

Indication for Use

510(k) Number (if known): k091845

Device Name: **EliA™ β2-Glycoprotein I IgM**

Indication For Use:

EliA β2-Glycoprotein I IgM is intended for the in vitro semi-quantitative measurement of IgM antibodies directed to β2-Glycoprotein I in human serum and plasma (Li-heparin, EDTA, citrate) to aid in the diagnosis of antiphospholipid syndrome (APS) as well as thrombotic disorders related to secondary antiphospholipid syndrome in conjunction with other laboratory and clinical findings. EliA β2-Glycoprotein I IgM uses the EliA IgM method on the instrument Phadia 250.

Prescription Use __√____ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Reena Philip

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k091845

Indication for Use

510(k) Number (if known): K091845

Device Name: **EliA™ APS Positive Control 100**

Indication For Use:

EliA APS Positive Control 100 is intended for laboratory use in monitoring the performance of in vitro measurement of antibodies to cardiolipin and ß2-Glycoprotein I with Phadia 100 using the EliA IgG or IgM method.

Prescription Use __√____ And/Or Over the Counter Use ____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Leena Philip

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K091845

Indication for Use

510(k) Number (if known): K091845

Device Name: **EliA™ APS Positive Control 250**

Indication For Use:

EliA APS Positive Control 250 is intended for laboratory use in monitoring the performance of in vitro measurement of antibodies to cardiolipin and ß2-Glycoprotein I with Phadia 250 using the EliA IgG or IgM method.

Prescription Use __√____ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Leena Philip

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K091845

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G6
Silver Spring, MD 20993-0002

Yen-Ming Pan
President
PANPAC Medical Corp.
6F-2, No. 202, SEC. 3, Ta-Tong Road
Shi-Chih City, Taipei Hsien, 22103
TAIWAN
R.O.C.

JUN - 7 2010

Re. K092983
Trade/Device Name: PANPAC HSG Catheter Set
Regulation Number: None
Regulatory Class: Unclassified
Product Code: LKF
Dated: May 3, 2010
Received: May 6, 2010

Dear Mr. Pan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K092983

Device Name: PANPAC HSG Catheter Set

Indications for Use:

PANPAC HSG catheter sets are indicated to evaluate the causes of abnormal uterine bleeding, menstrual disorders, recurring pregnancy loss, or unexplained infertility. They can also be used to assess uterine pathology and patients on tamoxifan therapy.

HSG type catheter sets are used to infuse a fluid (either a contrast media or a sterile saline) into the uterine cavity while blocking the external cervical os to retain the fluid in the uterus during the procedure.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____X____ OR Over-The-Counter Use _____

(Per 21 CFR 801. 109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K092983